

WHAT IS CLAIMED IS:

1. A method for transmyocardial coronary revascularization, said method comprising the step of:

5       a) creating a transmyocardial bloodflow passageway between a chamber of the heart and a coronary vein.

10      2. The method of Claim 1 wherein said passageway is formed such that blood will flow from the chamber of the heart, through the transmyocardial bloodflow passageway, and through the lumen of the coronary vein, in a retrograde direction, so as to perfuse said region of the myocardium.

15      3. The method of Claim 1 wherein said coronary vein is situated next to a coronary artery, and wherein said method further comprises the step of:

20       15     b) forming a fistulous connection between said coronary vein and said adjacent coronary artery, at a location which is downstream of said transmyocardial bloodflow passageway, such that blood may flow from the chamber of the heart, through said transmyocardial bloodflow passageway, through said vein, through said fistulous connection, and into the adjacent coronary artery so as to provide enhanced bloodflow through said coronary artery.

25      4. The method of Claim 3 wherein said fistulous connection is a secondary bloodflow passageway which extends from said coronary vein to said coronary artery.

30      5. The method of Claim 1, further comprising the additional step of:

35       30     b) blocking the lumen of the coronary vein at a location which is upstream of said transmyocardial bloodflow passageway.

6. The method of Claim 3 wherein said method further comprises the steps of:

blocking the lumen of the coronary vein at a location downstream of said fistulous connection.

35      7. The method of Claim 1 further comprising the step of:

35       35     b) placing an intraluminal valving apparatus within the lumen of the coronary vein, said intraluminal

bloodflow passageway, said tissue valve will move to its closed position.

16. The method of Claim 1 further comprising the step of:

5 connecting an elastic closure member to cardiac tissue on either side of said transmyocardial bloodflow passageway, said elastic closure member being alternately transitionable between:

- 10 i) a stretched configuration whereby said transmyocardial bloodflow passageway is opened to permit blood to flow from said transmyocardial bloodflow passageway into said coronary vein; and  
ii) a retracted configuration whereby said transmyocardial bloodflow passageway is substantially blocked so as to prevent blood from backflowing from said coronary vein into said transmyocardial bloodflow passageway.
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17. The method of Claim 16 wherein said elastic closure member comprises a suture which is formed of elastic material, said suture being threaded through said myocardial tissue on opposite sides of said transmyocardial bloodflow passageway.

18. The method of Claim 1 further comprising the step of:

25 b) placing an intracardiac valving apparatus within the chamber of the heart, adjacent one end of said transmyocardial bloodflow passageway, said intracardiac valving apparatus being alternately deployable in:

- 30 i) an open position whereby bloodflow is permitted to pass through the transmyocardial bloodflow passageway in a first direction; and,  
ii) a closed position whereby blood is prevented from backflowing through the transmyocardial bloodflow passageway, in a second

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12. The method of Claim 1 further comprising the step of:

c) forming an endogenous tissue valve which is alternately moveable between:

5 i) an open position whereby bloodflow is permitted to pass from said transmyocardial bloodflow passageway and through the lumen of said coronary vein, in a perfusion direction; and,

10 ii) a closed position whereby said tissue valve will prevent blood from flowing from the coronary vein into said transmyocardial bloodflow passageway, in a backflow direction.

13. The method of Claim 12 wherein said tissue valve is formed at the junction of the transmyocardial bloodflow 15 passageway and the coronary vein.

14. The method of Claim 13 wherein the tissue valve comprises at least one segment of the coronary vein in combination with at least one underlying segment of myocardial tissue.

20 15. The method of Claim 14 wherein at least one segment of coronary vein and the at least one segment of underlying tapered segment of myocardial tissue which form said tissue valve are sized and configured such that, when systolic blood pressure is created within said transmyocardial bloodflow 25 passageway, said tissue valve will move to its open position, and thereafter when diastolic blood pressure is present in said transmyocardial bloodflow passageway, said tissue valve will move to its closed position.

16. The method of Claim 1 further comprising the step 30 of:

connecting an elastic closure member to cardiac tissue on either side of said transmyocardial bloodflow passageway, said elastic closure member being alternately transitionable between:

35 i) a stretched configuration whereby said transmyocardial bloodflow passageway is opened to permit blood to flow from said transmyocardial bloodflow passageway into said coronary vein; and

5                   ii) a retracted configuration whereby said transmyocardial bloodflow passageway is substantially blocked so as to prevent blood from backflowing from said coronary vein into said transmyocardial bloodflow passageway.

17. The method of Claim 16 wherein said elastic closure member comprises a suture which is formed of elastic material, said suture being threaded through said myocardial tissue on opposite sides of said transmyocardial bloodflow passageway.

10                 18. The method of Claim 1 further comprising the step of:

15                 b) placing an intracardiac valving apparatus within the chamber of the heart, adjacent one end of said transmyocardial bloodflow passageway, said intracardiac valving apparatus being alternately deployable in:

20                 i) an open position whereby bloodflow is permitted to pass through the transmyocardial bloodflow passageway in a first direction; and,

25                 ii) a closed position whereby blood is prevented from backflowing through the transmyocardial bloodflow passageway, in a second direction, said second direction being opposite said first direction.

30                 19. The method of Claim 18 wherein said transmyocardial bloodflow passageway is intended to provide a flow of blood from the chamber of the heart to the coronary vein, and wherein said first direction is the direction extending from the chamber of the heart to the coronary vein, and said second direction is the direction extending from the coronary vein to the chamber of the heart.

35                 20. The method of Claim 18 wherein said transmyocardial bloodflow passageway is intended to drain blood from the coronary vein into the chamber of the heart, and wherein said first direction is the direction extending from the coronary vein to the chamber of the heart, and said second direction is the direction extending from the chamber of the heart to the coronary vein.

21. The method of Claim 18 wherein the intracardiac valving apparatus provided in step b is attached to the wall of the chamber of the heart, and is positioned over the opening formed in the chamber of the heart by said  
5 transmyocardial bloodflow passageway.

22. The method of Claim 21 wherein said intracardiac valving apparatus is sutured to the wall of the chamber of the heart.

23. The method of Claim 21 wherein said intracardiac  
10 valving apparatus is adhered to the wall of the chamber of the heart.

24. The method of Claim 1 further comprising the step of:

15 b) placing a protrusive stent within said transmyocardial passageway, such that said protrusive stent extends into said coronary vein.

25. The method of Claim 24 wherein said protrusive stent is uncovered.

26. The method of Claim 24 wherein said protrusive stent is at least partially covered.

27. The method of Claim 24 wherein said protrusive stent incorporates at least one valve to intermittently block blood flow, in at least one direction, through said transmyocardial passageway.

25 28. The method of Claim 27 wherein said valve is operative to permit blood to flow from said chamber of the heart through said transmyocardial passageway, and into said coronary vein, but will prevent blood from backflowing from said coronary vein into said transmyocardial passageway.

30 29. A method for transmyocardial direct coronary revascularization, said method comprising the steps of:

a) forming a transmyocardial bloodflow passageway from a chamber of the heart to a coronary blood vessel;

35 b) permitting blood to flow from the chamber of the heart, through said transmyocardial bloodflow passageway; and

c) into the coronary blood vessel, while said transmyocardial bloodflow passageway remains devoid of any stent positioned therewithin.

30. The method of Claim 29 wherein said blood vessel is  
5 selected from the group consisting of:

i) an endogenous coronary artery;

ii) an endogenous coronary vein;

. iii) a man-made passageway which has been formed  
10 in the heart and which connects to an endogenous  
coronary vein;

iv) a man-made passageway which has been formed  
15 in the heart and which connects to an endogenous  
coronary artery; and

v) a man-made passageway which extends between  
15 an endogenous coronary artery and an endogenous coronary  
vein.

31. The method of Claim 29 wherein said coronary blood  
vessel is an endogenous coronary vein which is situated next  
20 to a coronary artery, and wherein said method further  
comprises the step of:

d) forming a second bloodflow passageway between  
said coronary vein and the adjacent coronary artery, at  
a location which is downstream of said transmyocardial  
bloodflow passageway.

25 32. The method of Claim 31 wherein said second bloodflow  
passageway is a fistulous tract which extends between said  
coronary vein and said coronary artery.

33. The method of Claim 29 wherein it is intended for  
blood to flow in a first flow direction through said coronary  
30 blood vessel and wherein said method further comprises the  
additional step of:

d) blocking the lumen of the coronary blood  
vessel at a location which is upstream of said  
transmyocardial bloodflow passageway.

35 34. The method of Claim 31 wherein said method further  
comprises the step of:

d) blocking the lumen of the coronary vein  
downstream of said fistulous connection.

35. The method of Claim 29 further comprising the step of:

5 d) placing an intraluminal valving apparatus within the lumen of the coronary blood vessel, said intraluminal valving apparatus comprising at least one occluder member which is alternately deployable in:

10 i) an open position whereby bloodflow is permitted to pass from said transmyocardial bloodflow passageway and through the lumen of the coronary vein in a perfusion direction; and,

15 ii) a closed position whereby blood is prevented from flowing from the coronary vein into said transmyocardial bloodflow passageway, in a backflow direction.

20 36. The method of Claim 35 wherein the intravascular valving apparatus of step C is positioned downstream of the transmyocardial bloodflow passageway, and wherein said method further comprises the step of:

25 e) blocking the lumen of the coronary vein upstream of the transmyocardial bloodflow passageway.

30 37. The method of Claim 29 further comprising the step of:

c) forming an endogenous tissue valve which is alternately moveable between:

25 i) an open position whereby bloodflow is permitted to pass from said transmyocardial bloodflow passageway and through the lumen of said coronary vessel, in a first direction; and,

30 ii) a closed position whereby said tissue valve will prevent blood from flowing from the coronary vein into said transmyocardial bloodflow passageway, in a second direction opposite said first direction.

35 38. The method of Claim 37 wherein said tissue valve is formed at the junction of the transmyocardial bloodflow passageway and the coronary blood vessel.

39. The method of Claim 38 wherein the tissue valve comprises at least one segment of the coronary blood vessel in

combination with at least one underlying segment of myocardial tissue.

40. The method of Claim 37 wherein at least one segment of coronary blood vessel and at least one underlying tapered 5 segment of myocardial tissue which form said valving tissue valve are sized and configured such that, when systolic blood pressure is created within said transmyocardial bloodflow passageway said tissue valve will move to its open position, and thereafter when diastolic blood pressure is present in 10 said transmyocardial bloodflow passageway, said tissue valve will move to its closed position.

41. The method of Claim 29 further comprising the step of:

15 connecting an elastic closure member to the myocardial tissue on either side of said transmyocardial bloodflow passageway, said elastic closure member being alternately transitioning between:

20 i) a stretched configuration whereby an opening is formed to permit blood to flow from said transmyocardial bloodflow passageway into said coronary vein; and

25 ii) a retracted configuration whereby said opening is substantially closed, thereby preventing blood from backflowing from said coronary vein into said transmyocardial bloodflow passageway.

42. The method of Claim 41 wherein said elastic closure member is a suture which is formed of elastic material and passed through said myocardial tissue on opposite sides of said transmyocardial bloodflow passageway.

30 43. The method of Claim 29 further comprising the step of:

b) placing a protrusive stent within said transmyocardial passageway, such that said protrusive stent extends into said coronary vessel.

35 44. The method of Claim 43 wherein said protrusive stent is uncovered.

45. The method of Claim 43 wherein said protrusive stent is at least partially covered.

46. The method of Claim 43 wherein said protrusive stent incorporates at least one valve to intermittently block blood flow, in at least one direction, through said transmyocardial passageway.

5 47. The method of Claim 46 wherein said valve is operative to permit blood to flow from said chamber of the heart through said transmyocardial passageway, and into said coronary vessel, but will prevent blood from backflowing from said coronary vein into said transmyocardial passageway.

10 48. An intraluminal valving apparatus which is operative to prevent blood from a backflowing from a coronary blood vessel into a transmyocardial bloodflow passageway which extends from a chamber of the heart to said coronary blood vessel, said apparatus comprising:

15 a generally cylindrical body having an axial bore which extends longitudinally therethrough; and,

at least one occluder member positioned within said axial bore, said at least one occluder member being alternately moveable between:

20 i) an open position whereby systolic blood is permitted to pass from said transmyocardial bloodflow passageway, through the lumen of the coronary blood vessel; and,

25 ii) a closed position whereby blood is prevented from backflowing from the lumen of the coronary blood vessel into the transmyocardial bloodflow passageway.

49. The valving apparatus of Claim 48 wherein said generally cylindrical body is initially of a radially compact diameter so as to be transluminally advanceable through the vasculature into said blood vessel, and is subsequently expandable to a second radially expanded diameter wherein said cylindrical body will contact and engage the surrounding wall of said blood vessel.

35 50. The valving apparatus of Claim 49 wherein said cylindrical body is self-expanding.

51. The valving apparatus of Claim 49 wherein said cylindrical body is pressure-expandable.

52. The valving apparatus of Claim 48 further comprising:

5 a side aperture formed in the cylindrical body of said apparatus, said side aperture being alienable with said transmyocardial bloodflow passageway such that blood from said transmyocardial bloodflow passageway may flow through said side aperture and into the axial bore of the valving apparatus.

10 53. The valving apparatus of Claim 52 wherein said at least one occluder member is configured to close off said side aperture when in its closed position, and further such that a subsequent increase in blood pressure within the transmyocardial bloodflow passageway will move said occluder member to said open position, thereby reopening said side aperture.

15 54. The valving apparatus of Claim 53 wherein said at least one occluder member is positioned within the axial bore of the apparatus, at a location downstream of said side aperture, such that systolic bloodflow which passes from the 20 transmyocardial bloodflow passageway into the axial bore of the apparatus will force said occluder member to its open position, thereby causing the bloodflow to continue in the downstream direction, and the subsequent creation of diastolic blood pressure is within the transmyocardial bloodflow 25 passageway will move said occluder member to its closed position thereby preventing blood from backflowing out of said side aperture and into said transmyocardial bloodflow passageway.

30 55. The valving apparatus of Claim 53 further comprising:

a blocking member which closes off the axial bore of the apparatus, upstream of said side aperture.

56. The valving apparatus of Claim 48 further comprising:

35 a secondary occluder member which closes off the axial bore of the apparatus, upstream of said side aperture.

57. The valving apparatus of Claim 48 wherein the apparatus is intended to be positioned within said coronary blood vessel at a location downstream of said junction between said blood vessel and said transmyocardial bloodflow passageway, and wherein:

5                   said at least one occluder member which is configured to permit blood to flow in a perfusion direction through said axial bore, when said at least one occluder member is in its open position, and to prevent blood from backflowing through said axial bore in a backflow direction, when said occluder member is in its closed position.

10                 58. A system comprising two of the valving apparatus of Claim 48, one of said valving apparatus being positionable within said coronary blood vessel upstream of said transmyocardial bloodflow passageway, and the other of said valving apparatus being positionable within said coronary blood vessel downstream of said transmyocardial bloodflow passageway.

15                 59. An intracardiac valving apparatus which is operative to control bloodflow through a transmyocardial bloodflow passageway extending from a chamber of the heart to a coronary blood vessel, said intracardiac valving apparatus comprising:

20                 25                 a valve body having an opening formed therethrough, said valve body being positionable in contact with the wall of the heart such that the opening of said valve body is in alignment with said transmyocardial bloodflow passageway;

25                 30                 at least one occluder member positioned within the opening of said valve body, said occluder member being alternately moveable between:

- 35                 i) an open position whereby blood is permitted to pass through said transmyocardial bloodflow passageway in a first direction; and,
- ii) a closed position whereby blood is prevented from flowing through said transmyocardial

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passageway in at least a second direction opposite said first direction.

60. The intracardiac valving apparatus of Claim 59 wherein said apparatus further comprises:

5 means for holding said intracardiac valving apparatus in substantial fixed position against said wall of the chamber of the heart.

61. The intracardiac valving apparatus of Claim 60 wherein said means for holding comprises hooks.

10 62. The intracardiac valving apparatus of Claim 61 wherein said means for holding comprises sutures.

63. The intracardiac valving apparatus of Claim 61 wherein said means for holding comprises an adhesive.

15 64. The intracardiac valving apparatus of Claim 61 wherein said means for holding comprises a retainer assembly which engages the heart, and which exerts force upon said intracardiac valving apparatus to hold said intracardiac valving apparatus to hold said intracardiac valving apparatus in substantially fixed position.

20 65. The intracardiac valving apparatus of Claim 64 wherein said retainer assembly comprises:

25 a generally annular retainer ring having an aperture formed therein, said generally annular retainer ring positionable within the coronary blood vessel such that the aperture formed therein is in alignment with the transmyocardial passageway; and,

30 at least one elastomeric tether member having a first end connected to said intracardiac valving apparatus and a second end connected to said retainer ring, said elastomeric tether member being of a length and resiliency which is sufficient to exert sufficient inward pressure upon said valving apparatus and said retainer ring to hold said valving apparatus and said retainer ring in substantially fixed positions, with the aperture of the valving apparatus and the aperture of the retainer ring being in alignment with said transmyocardial passageway.

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66. A protrusive stent apparatus for stenting a transmyocardial passageway which extends from a chamber of the heart to a coronary blood vessel, said apparatus comprising:  
a tubular body which is alternately configurable

5 in:

i) a radially collapsed configuration of a first diameter;

10 ii) a radially expanded configuration of a second diameter, said second diameter being at least as large as the diameter of the transmyocardial passageway;

15 said protrusive stenting apparatus having a length which is longer than the length of the transmyocardial passageway, such that said apparatus may be positioned within said transmyocardial passageway from said cardiac chamber to said coronary blood vessel, with a portion of said apparatus protruding into said coronary blood vessel.

67. The protrusive stent apparatus of Claim 66 wherein  
20 the tubular body of said stent apparatus is self-expanding.

68. The protrusive stent apparatus of Claim 66 wherein the tubular body of said stent apparatus is pressure expandable.

69. The protrusive stent apparatus of Claim 66 wherein  
25 the tubular body of said stent apparatus is formed of material selected from the group of materials consisting of:

metal;

polymeric material.

70. The apparatus of Claim 66 wherein said apparatus  
30 further comprises:

a tubular covering formed on said stent.

71. The apparatus of Claim 70 wherein said tubular covering is formed of a material selected from the group of materials consisting of:

35 polyester;

woven polyester;

polytetrafluroethylene;

expanded polytetrafloueroethylene;

polyurethane;  
silicone;  
polycarbonate;  
autologous tissue; and,  
5                   xenograft tissue.

72. The apparatus of Claim 66 wherein said apparatus further comprises:

at least one valve positioned within said tubular body to control bloodflow therethrough.

10                 73. A method for transmyocardial coronary revascularization of a coronary artery having an occlusion formed therein, said method comprising the steps of:

15                 a) providing a passageway-forming catheter comprising an elongate pliable catheter body having at least one tissue-penetrating element which is passable from the catheter body to form an interstitial passageway through tissue;

20                 b) inserting the passageway-forming catheter into the venous vasculature and advancing the catheter until a distal portion of the catheter is located within a coronary vein adjacent the coronary artery wherein the obstruction is present;

25                 c) orienting the passageway-forming catheter such that the tissue-penetrating element is directed toward the coronary artery at a site downstream of the obstruction;

30                 d) passing the tissue-penetrating element from the passageway-forming catheter, through the wall of the coronary vein wherein the catheter is positioned, through any tissue located between the coronary vein and the coronary artery, through the wall of the coronary artery and into the coronary artery, downstream of the obstruction, thereby forming an arterio-venous passageway between said coronary artery and said coronary vein;

35                 e) advancing the passageway-forming catheter through the arterio-venous passageway and into the coronary artery, downstream of the obstruction;

f) orienting the passageway-forming catheter such that the tissue-penetrating element is directed toward a chamber of the heart;

5 g) passing the tissue-penetrating element from the passageway-forming catheter, through the wall of the coronary artery, through the myocardium and into a chamber of the heart, thereby forming a transmyocardial passageway through which blood may flow from the chamber of the heart and into the coronary artery, downstream of the obstruction;

10 h) removing the passageway-forming catheter from the body;

i) closing the arterio-venous passageway which had been formed in step d.

15 74. The method of Claim 73 wherein step i comprises placing an occlusion apparatus within said arterio-venous passageway.

20 75. The method of Claim 73 wherein step i comprises applying energy to the tissue surrounding said arterio-venous passageway to close said arterio-venous passageway.

76. The method of Claim 75 wherein the energy utilized to close said arterio-venous passageway is selected from the group of energy types consisting of:

electrocautery, heat, radiofrequency, and light.

25 77. A method for treating myocardial ischemia, said method comprising the steps of:

30 a) providing an intravascular valving apparatus, said apparatus comprising a frame which is engageable with a surrounding vascular wall and at least one occluder mounted in said frame, said occluder being alternately moveable between a closed position wherein said occluder will block the flow of blood in an outflow direction through said coronary vein, in an open position wherein said occluder will permit blood to flow in said outflow direction through said coronary vein, said occluder being biased to its closed position but being moveable to its open position when the pressure of

blood within the coronary vein exceeds a predetermined maximum pressure;

5 b) implanting the intravascular valving apparatus at a first location within the coronary venous vasculature such that the occluder member of said valving apparatus will prevent the flow of blood in an outflow direction from at least one coronary vein until such time as the pressure of blood within that coronary vein exceeds said predetermined maximum pressure.

10 78. The method of Claim 77 wherein said method further comprises:

15 forming a transmyocardial passageway from said coronary vein to a chamber of the heart such that blood may flow from the chamber of the heart, through the transmyocardial passageway, and into the coronary vein.

20 79. The method of Claim 78 wherein said myocardial passageway is formed between the left ventricle of the heart and said coronary vein such that oxygenated blood from the left ventricle will flow through the transmyocardial passageway and into the coronary vein.

80. The method of Claim 77 wherein the intravascular valving apparatus is implanted within the coronary sinus.

81. The method of Claim 77 wherein the intravascular valving apparatus is implanted within the great cardiac vein.

25 82. A method for performing an intraluminal medical procedure within the lumen of an obstructed coronary artery, at a site downstream of the obstruction, said method comprising the steps of:

30 a) providing a passageway-forming catheter comprising an elongate pliable catheter body having at least one tissue-penetrating element which is passable from the catheter body to form an interstitial passageway through tissue;

35 b) inserting the passageway-forming catheter into the venous vasculature and advancing the catheter until a distal portion of the catheter is located within a coronary vein adjacent the coronary artery wherein the obstruction is present;

c) orienting the passageway-forming catheter such that the tissue-penetrating element is directed toward the coronary artery at a site downstream of the obstruction;

5                   d) passing the tissue-penetrating element from  
the passageway-forming catheter, through the wall of the  
coronary vein wherein the catheter is positioned,  
through any tissue located between the coronary vein and  
the coronary artery, through the wall of the coronary  
artery and into the coronary artery, downstream of the  
obstruction, thereby forming an arterio-venous  
passageway between said coronary artery and said  
coronary vein;

15 e) passing an apparatus through said arterio-  
venous passageway and into the lumen of the coronary,  
downstream of the obstruction, and utilizing said  
apparatus to perform said intraluminal procedure;

20 f) removing the apparatus from the coronary artery, through said arterio-venous passageway; and closing the arterio-venous passageway which had been formed in step d.

83. The method of Claim 82 wherein said intraluminal procedure is selected from the group of intraluminal procedures consisting of:

25 an atherectomy procedure wherein a passageway is  
formed through the occlusion in the coronary;

an ablation procedure wherein the obstruction in the coronary artery is ablated;

30 a thrombolytic procedure wherein a thrombus within  
the coronary artery is lysed; .

a stenting procedure wherein a stent is placed in the lumen of the coronary artery downstream of the obstruction;

35 a revascularization procedure wherein a blood flow  
passageway is formed between said coronary artery at a  
site downstream of the obstruction to another blood-  
containing anatomical structure such that blood may flow

into said coronary artery at a site downstream of the obstruction; and,

5 a target apparatus deployment procedure wherein a target apparatus is positioned within the lumen of the coronary artery downstream of the obstruction so as to facilitate targeting of said coronary artery downstream of the obstruction by another device.

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